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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,640	TÜRECI ET AL.	
	Examiner	Art Unit	
	MARIANNE DIBRINO	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/13/06,2/9/07,10/18/07,10/22/10*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 19-42* is/are pending in the application.

4a) Of the above claim(s) *9,10 and 19-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 11* is/are rejected.

7)☒ Claim(s) *42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/8/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Notice to Comply with the Sequence Requirements.

DETAILED ACTION

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. In particular, SEQ ID NO are required for SEQ ID NO appearing in Figure 8.

Applicant is advised that for any response to be considered fully responsive said response has to be fully responsive to the sequence compliance requirements.

2. Applicant's amendment and response filed 10/22/10 is acknowledged and has been entered.

3. Applicant's election with traverse of Group I and species of SEQ ID NO: 12, which is comprised of SEQ ID NO: 4 present at amino acid residues 599-653 of SEQ ID NO: 12 that encodes an HLA class I molecule transmembrane and cytoplasmic regions, and SEQ ID NO: 10 which is human CMV phosphoprotein pp65 which is present at amino acid positions 36-596 of SEQ ID NO: 12, in the amendment and response filed 10/22/10 is acknowledged.

The basis for Applicant's traversal is of record on pages 7-9 of Applicant's amendment and response filed 10/22/10.

Applicant's arguments have been fully considered but are not persuasive.

Applicant's allegation that the restriction requirement did not provide a rationale on the record to support a restriction requirement is not persuasive. "If the Examiner finds that a national stage application lacks unity of invention under 1.475, the examiner may in an Office action require the applicant in the response to that action to elect the invention to which the claims shall be restricted." See MPEP 1893.03(d). Item #2 in the Office Action mailed 7/22/10 established a lack of unity of invention of the instant application. With regard to Applicant's argument that two requirements for restriction as stated in MPEP 808 (i.e., independent or distinct and serious burden), Applicant is reminded that unity of invention (not restriction practice pursuant to 37 CFR 1.141-1.146) is applicable in national stage applications submitted under 35 USC 371 (*ibid*).

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-8, 11 and 42 read on the elected species.

Accordingly, claims 9, 10 and 19-41 (non-elected groups II-VII) are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claims 1-8, 11 and 42 are currently being examined.

4. The disclosure is objected to because of the following informality: The Brief Description of the Drawings for Figure 8 does not disclose the SEQ ID NO appearing in corresponding Figure 8.

Appropriate correction is required.

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 8 recites the limitation "antigen portion thereof comprises a plurality of antigens" in line 1. There is insufficient antecedent basis for this limitation in the claim as base claim 1 recites only “which comprises an antigen.”

8. For the purpose of prior art rejections, the filing date of the instant claims is deemed to be the filing date of PCT/EP04/11512*, i.e.,* 10/13/04, as a certified English language translation has not been provided for Germany 10347710.1.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1 and 3-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhode *et al* (J. Immunol. 1996, 157: 4885-4891, of record).

It is noted by the Examiner that the instant specification discloses that “derived” indicates that a sequence is present in the object from which it is derived, such as the object being a molecule (see in particular, the paragraph spanning pages 24-25).

Rhode *et al* teach a MHC fusion protein that comprises a MHC leader peptide, an antigen, a transmembrane region and a cytoplasmic region of a chain of said MHC molecule (especially Figure 1 and the first paragraph at column 1 on page 4889).

Note that instant claim 1 does not recite that the fusion protein is isolated, and the open transitional phrase "comprising" renders the claim open to other non-recited components such as the alpha and beta chains of MHC, as well as the leader sequence.

Claim 7 is included in this rejection because the claim merely recites the "arrangement of segments" but does not recite that the listed segments are directly contiguous with one another in the recited order. Said claim also recites that the individual segments may be optionally separated from one another by linker sequences.

11. Claims 1-7 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/25054 A1 (IDS reference).

It is noted by the Examiner that the instant specification discloses that "derived" indicates that a sequence is present in the object from which it is derived, such as the object being a molecule (see in particular, the paragraph spanning pages 24-25).

WO 94/25054 A1 teaches a recombinant protein which is an MHC class I heavy chain wherein the alpha 1 and alpha 2 domains that form an antigen binding domain of the MHC molecule are substituted with a target amino acid sequence against which it is desired to induce an immune response (*i.e.,* an antigen), and said protein includes a leader sequence, transmembrane and cytoplasmic regions. WO 94/25054 A1 further teaches a vaccine comprising said protein, *i.e.,* a pharmaceutical composition comprising the protein and a pharmaceutically acceptable carrier as recited in instant claim 11 (see entire reference, especially page 13 at lines 5-9 and claims).

Note that instant claim 1 does not recite that the fusion protein is isolated, and the open transitional phrase "comprising" renders the claim open to other non-recited components.

Claim 7 is included in this rejection because the claim merely recites the "arrangement of segments" but does not recite that the listed segments are directly contiguous with one another in the recited order.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1, 3-7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhode *et al* (J. Immunol. 1996, 157: 4885-4891, of record) in view of US 20020110566 A1.

It is noted by the Examiner that the instant specification discloses that "derived" indicates that a sequence is present in the object from which it is derived, such as the object being a molecule (see in particular, the paragraph spanning pages 24-25).

Rhode *et al* teach a MHC fusion protein that comprises a MHC leader peptide, an antigen, a transmembrane region and a cytoplasmic region of a chain of said MHC molecule (especially Figure 1 and the first paragraph at column 1 on page 4889). Rhode *et al* teach that class II/peptide complexes have significant clinical relevance in antigen-specific treatment of immune disorders (last paragraph of reference).

Rhode *et al* do not teach that the protein is comprised in a composition containing a pharmaceutically acceptable carrier.

US 20020110566 A1 discloses that a pharmaceutically acceptable carrier for a protein is PBS or a bicarbonate solution ([0063]).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have placed the protein taught by Rhode *et al* in a pharmaceutically acceptable carrier such as one disclosed by US 20020110566 A1.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this because Rhode *et al* teach that the class II complexes have significant clinical relevance in treatment of immune disorders and US 20020110566 A1 discloses pharmaceutically acceptable carriers for proteins.

Note that instant claim 1 does not recite that the fusion protein is isolated, and the open transitional phrase "comprising" renders the claim open to other non-recited components such as the alpha and beta chains of MHC, as well as the leader sequence.

Claim 7 is included in this rejection because the claim merely recites the "arrangement of segments" but does not recite that the listed segments are directly contiguous with one another in the recited order. Said claim also recites that the individual segments may be optionally separated from one another by linker sequences.

14. SEQ ID NO: 12 is free of the art.

15. Claim 42 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

16. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ram Shukla, can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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